<u>**AMENDMENTS TO THE CLAIMS**</u>

The following listing of claims will replace all prior versions and listings of claims in the application.

LISTING OF CLAIMS

1.   (Original)   A method of designing an interbody fusion cage comprising:

defining operational parameters for the cage;

defining a macroscopic structural layout for the cage satisfying the operational parameters;

dividing the macroscopic structural layout of the cage into a plurality of discreet sub-segments;

defining a density distribution of the macroscopic structural layout by determining a density level for each sub-segment; and

defining a microscopic structural layout for the cage by assigning pre- selected microstructures to the sub-segments in accordance with the density level of each sub-segment.

2.   (Original)   The method of claim 1 wherein the operational parameters further comprise stability, porosity, and compliance.

3.   (Original)   The method of claim 1 wherein the step of defining the macroscopic structural layout further comprises executing a topology optimization algorithm for the cage based on the operational parameters.

4.   (Original)   The method of claim 1 wherein the step of defining the microscopic structural layout further comprises executing a topology optimization algorithm for the cage based on the density distribution.

5.   (Original)   The method of claim 1 further comprising integrating the microscopic structural layout and the macroscopic structural layout to provide a designed cage.

6.   (Original)   The method of claim 1 further comprising manufacturing the designed cage with solid free-form fabrication techniques.

7.   (Original)   The method of claim 1 further comprises categorizing the sub-segments into different ranks based on the density level of each sub-segment, each rank being defined by a different length scale; and

homogenizing the microstructure of a particular rank to an upper rank.

8.   (Original)   A method of designing an interbody fusion cage comprising:

modeling a mechanical environment in which the cage is to be used;

performing a macroscopic layout topology optimization process to define a global layout topology solution for the cage;

performing a density distribution process on the global layout topology solution to define a density distribution of the global layout topology;

performing a microscopic layout topology optimization process to define a microstructure topology solution according to the density distribution; and   integrating the macroscopic and microscopic topology solutions.

9.   (Original)   The method of claim 8 wherein the step of modeling the mechanical environment further comprises creating a finite element model to simulate the mechanical environment.

10.   (Original)   The method of claim 8 wherein the step of performing a microscopic layout topology optimization process to define a microstructure topology solution according to the density distribution further comprises representing microstructures of sub-segments of the cage with intermediate density values from the global topology optimization solution, the microstructures being defined at different length scales than the scale of the global optimization solution.

11. (Original) The method of claim 8 wherein the step of performing a microscopic layout topology optimization process to define a microstructure topology solution according to the density distribution further comprises:

employing a low resolution mesh with a homogeneous density as a first initial guess in the optimization process;

solving an optimization problem for the low resolution mesh to yield a rough solution;

meshing the rough solution at a finer resolution to yield a finer resolution solution;

using the finer resolution solution as a subsequent initial guess in the optimization problem; and

repeating the above steps until a finest resolution solution is provided.

12.　(Original)　The method of claim 8 wherein the step of performing a microscopic layout topology optimization process to define a microstructure topology solution according to the density distribution further comprises:

defining one of stiffness and porosity as an objective function of the cage and the other of stiffness and porosity as a design variable;

inputting material constraints for the cage based on the objective function;

inputting a low resolution mesh of the microstructure topology based on the objective function as an initial guess design;

homogenizing the material constraints and calculating sensitivity functions for the initial guess design;

determining if a convergence of the objective function is achieved by the initial guess design;

if convergence is not achieved:

solving a topology optimization problem in the optimization process using a method of moving asymptotes;

updating the design variable in the initial guess design; and

repeating until convergence of the objective function is achieved;

once convergence is achieved, filtering the initial guess design;

determining whether a finest mesh size has been achieved within the initial guess design;

if the finest mesh size is not achieved, updating the material constraints and refining the low resolution mesh to yield an updated initial guess;

applying image processing filtering techniques to the updated initial guess;

providing the image processing filtered initial guess for a smaller mesh size as a new initial guess design; and

repeating the above steps until the finest mesh size is achieved.

13.   (Original)   The method of claim 12 further comprising performing heuristic random rounding filtering on the finest mesh size design to yield a final design layout.

14.   (Original)   The method of claim 12 wherein the image processing technique eliminates checkerboard density patterns.

15.   (Original)   The method of claim 14 wherein the image processing technique employs a Gaussian smoothing filter and a connectivity filter to smooth sub-segment densities within the cage relative to surrounding sub-segments.

16.   (Original)   The method of claim 12 wherein the stiffness objective function further comprises:

Objective function:

$$\underset{E^{scaffold},d_1,d_2,d_3}{\text{Min}} \left\{ \sum_{i=1}^{n} \left(\frac{C_i^{bone\ eff} - C_i^{tissue\ eff}}{C_i^{bone\ eff}} \right)^2 + \sum_{i=1}^{n} \left(\frac{C_i^{bone\ eff} - C_i^{scaffold\ eff}}{C_i^{bone\ eff}} \right)^2 \right\}.$$

Where n = 1-9.

Constraints:

$d_1, d_2, d_3 \leq 900\ \mu m$

$d_1, d_2, d_3 \geq 300\ \mu m$

$\underline{V\text{pore}}$

$V\text{total} \geq \%\ \text{Porosity},$

$E^{scaffold} \geq E\text{min},$

$E^{scaffold} \leq E\text{max},$

wherein the material constraints include:

$E^{scaffold}$ as the scaffold base material Young's modulus;

d_1, d_2, and d_3 as three cylindrical diameters of pores within the microstructure;

$C^{bone\ eff}$ as the effective stiffness of the target bone;

$C^{tissue\ eff}$ as the regenerate tissue effective stiffness; and

$C^{scaffold\ eff}$ as the scaffold effective stiffness.

17.   (Original)   The method of claim 12 wherein the porosity objective function further comprises:

Objective function:

$$\underset{E^{scaffold},\, d_1,\, d_2,\, d_3}{\text{Max}} \quad \frac{V_{pore}}{V_{total}},$$

Constraints:

$$x_1 \, C_i^{bone\ eff} \leq C_i^{tissue\ eff} \leq x_2 \, C_i^{bone\ eff}$$

where $i = 1\text{-}9$; $x_2 > x_1$,

$$\beta_1 \, C_i^{bone\ eff} \leq C_i^{scaffold\ eff} \leq \beta_2 \, C_i^{bone\ eff}$$

where $i = 1\text{-}9$; $\beta_2 > \beta_1$,

$$d_1, d_2, d_3 \leq 900 \ \mu m,$$

$$d_1, d_2, d_3 \geq 300 \ \mu m,$$

$$E^{scaffold} \geq E_{min},$$

$$E^{scaffold} \leq E_{max},$$

wherein α_1, α_2, β_1 and β_2 are scaling factors used to bound the cage and regenerate tissue effective stiffness and the material constraints include:

$E^{scaffold}$ as the scaffold base material Young's modulus;

d_1, d_2, and d_3 as three cylindrical diameters of pores within the microstructure;

$C^{bone\ eff}$ as the effective stiffness of the target bone;

$C^{tissue\ eff}$ as the regenerate tissue effective stiffness; and

$C^{scaffold\ eff}$ as the scaffold effective stiffness.

18. (Original)   A method of designing an interbody fusion cage comprising:

generating a global density distribution under physiologic loading for the cage using a global topology optimization algorithm including:

a stability constraint that limits total displacement of the cage at a desired surface to be less than a target value; and

a total porosity constraint that ensures desired biofactor delivering ability and compliance;

segmenting the global density distribution architecture into a plurality of regions, each region having a material phase selected from:

a low porosity solid phase;

a high porosity solid phase; and

a voided phase; and

defining a porous microstructure for the cage by generating periodic microstructures for the regions having the high porosity solid phase and low porosity solid phase using a microstructure topology optimization method.

19. (Original)   The method of claim 18 wherein:

the low porosity solid phase regions are about 45%~55% solid;

the high porosity solid phase regions are about 20%~35% solid; and

the voided phase regions are about 0% solid.

20. (Original) The method of claim 18 wherein the step of defining a porous microstructure for the cage further comprises achieving Hashin-Shtrikman stiffness bounds for porous isotropic materials.